K092030

DENTSPLY

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510(k) SUMMARY
for
Elation MB Metal Reinforced Plastic Brackets

1. Submitter Information:

DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405

Contact Person: Helen Lewis
Telephone Number: 717-849-4229
Fax Number: 717-849-4343

JUL 24 2009

Date Prepared: 2 July 2009

2. Device Name:
   - Proprietary Name: Elation MB Metal Reinforced Plastic Brackets
   - Classification Name: Bracket Plastic Orthodontic
   - CFR Number: 872.5470
   - Device Class: II
   - Product Code: DYW

3. Sponsor's Predicate Device:

Company	Device	510(k) Number	Date Cleared
GAC International	Elation	K942826	12/14/1994
DENTSPLY International Inc	Mystique MB Ceramic Bracket	K082974	11/07/2008
DENTSPLY International Inc	Allure MB Ceramic Brackets	K090454	03/20/2009

4. Description of Device:

The marketed product Elation Metal Reinforced Plastic Brackets has a barrel polished bonding base. A modification has been made to replace the base with the previously tested mechanical lock base and an improvement in the tie wing, Elation MB Metal Reinforced Plastic Brackets.

5. Indications for Use:

Elation MB is indicated for orthodontic movement of natural teeth.

6. Description of Safety and Substantial Equivalence:

Technological Characteristics.

The Elation MB metal reinforced plastic brackets represents a modification to K942826.

All of the components found in Elation MB Metal Reinforced Plastic Brackets have been used in legally marketed devices and/or were found safe for dental use. Elation MB Metal Reinforced Plastic Brackets have the same composition as the predicate devices. Therefore, further biocompatibility testing is not necessary.

We believe that the prior use of the component of Elation MB Metal Reinforced Plastic Brackets in legally marketed devices, the performance data provided, and the biocompatibility data provided support regarding the safety and effectiveness of Elation MB Metal Reinforced Plastic Brackets for the indicated uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 24 2009

Ms. Helen Lewis
Director of Corporate Compliance and Regulatory Affairs
DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Street, Suite 60
York, Pennsylvania 17405-0872

Re: K092030
Trade/Device Name: Elation MB Metal Reinforced Plastic Brackets
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: DYW
Dated: July 2, 2009
Received: July 6, 2009

Dear Ms. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

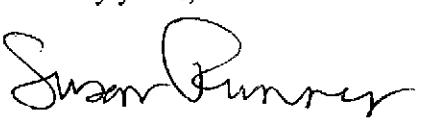
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K092030

Device Name: Elation MB metal reinforced plastic brackets

Indications for Use:

Elation MB metal reinforced plastic brackets is indicated for orthodontic movement of natural teeth.

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulry for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K 092030